

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
15 February 2001 (15.02.2001)

PCT

(10) International Publication Number
WO 01/10480 A1

(51) International Patent Classification⁷: A61L 31/06

(21) International Application Number: PCT/NL00/00555

(22) International Filing Date: 7 August 2000 (07.08.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
99202597.3 6 August 1999 (06.08.1999) EP

(71) Applicant (for all designated States except US): ISOTIS
B.V. [NL/NL]; Prof. Bronkhorstlaan 10, NL-3723 MB
Bilthoven (NL).

(72) Inventors; and

(75) Inventors/Applicants (for US only): BEZEMER,
Jeroen, Mattijs [NL/NL]; Milosdreef 51, NL-3562 VG
Utrecht (NL). DE WIJN, Joost, Robert [NL/NL]; Berg en

Dalseweg 80, NL-6522 BP Nijmegen (NL). NIEUWEN-
HUIS, Jan [NL/NL]; Aagje Dekenstraat 6, NL-4207 KD
Gorinchem (NL). DE JOODE, Paul, Carel, Hubertus
[NL/NL]; Grebbeweg 29, NL-3911 AS Rhenen (NL).
VAN BLITTERSWIJK, Clemens, Antoni [NL/NL];
Hekendorpse Buurt 2, NL-3467 PD Hekendorp (NL).

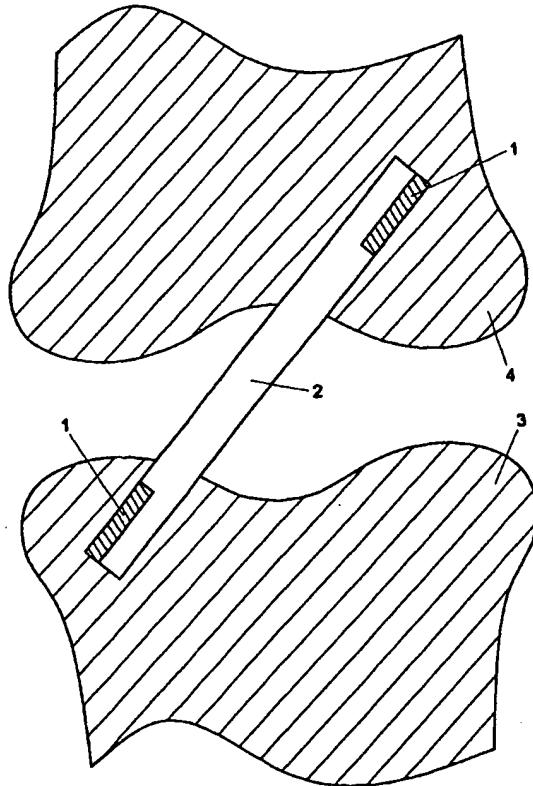
(74) Agent: PRINS, A., W.; Vereenigde, Nieuwe Parklaan 97,
NL-2587 BN The Hague (NL).

(81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ,
DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR,
HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR,
LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ,
NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM,
TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian

[Continued on next page]

(54) Title: FIXATIVE DEVICE



WO 01/10480 A1

(57) Abstract: The invention relates to a fixative device
for bone tissue, which device comprises a copolymer of a
polyalkylene glycol and an aromatic polyester.



patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

With international search report.

Title: Fixative device

The invention relates to a fixative device for attachment of tissues, in particular for attachment of soft tissue to bony tissue.

In surgery, many different fixative devices for tissue are used. Well-known examples include sutures, bone screws, suture anchors, clips, pins, 5 staples, and the like.

Bone screws are widely used as temporary medical implants for the fixation of skeletal fractures and/or for the fixation of orthopaedic implants. Important areas of application are fixation of the spinal cord after a geometric correction, healing of fractures in the knee, heel, elbow or hip, and fixation of 10 hip prostheses. Bone screws are generally made of a metallic material, e.g. of titanium, cobalt-chromium alloys, and stainless steel. Recently, however, some biodegradable, synthetic polymers, such as polymers of lactic acid, have been employed for manufacturing bone screws. An important property the materials should possess, is an excellent biocompatibility in contact with bone and 15 surrounding tissues.

Suture anchors are devices which are increasingly used, particularly in trauma and sports surgery, for fixing soft tissue, such as muscle or ligament tissue, to hard tissues, such as (cortical) bone tissue. These devices generally consist of two parts. One part is a screw-like device, e.g. a bone screw, which is 20 fixed to the hard tissue by providing a cavity in the hard tissue and by tapping screw thread in the sidewalls of the cavity for cooperation with the screw thread of the screw bone screw; the other is a device which is attached to the screw-like device and may be connected to soft tissue. Often, the latter device is a suture-like material made of a multifilament or monofilament, 25 biodegradable material, such as Biosyn™, Monocryl™, Vicryl™ or Dexon™.

Another manner of attaching soft tissue to bony tissue concerns the use of the Anterior Cruciate Ligament (ACL) system. To this end, a hole is drilled in the tibia and/or femur, in the sidewalls of which screw thread is

subsequently tapped. In this hole, the ligament is placed, and fixed in position by a screw which is applied over the ligament.

Recently, there has been a trend to use a biodegradable material, instead of a metallic material, for the manufacture of the above fixative devices. Examples of proposed biodegradable materials in this regard are polyglycolides, polylactides and blends or copolymers thereof. The great advantage of the devices being of a biodegradable material is that the material decomposes after a predetermined period of time. This means that it is not necessary to remove the device when its presence is no longer needed, and that 10 a surgical removal procedure may be omitted. Of course, the rate of degradation of the material should be chosen such that sufficient mechanical strength is provided by the device until the presence of the device is no longer needed.

As has been indicated above, the connection of the various fixative 15 devices to bone tissue is generally based on the use of screw-thread. A serious disadvantage of this manner of connecting the device to bone tissue, is that the cavity, into which the device is to be fixed, needs to be provided with screw-thread in order to provide the connection with sufficient mechanical strength. The tapping of screw thread constitutes an additional surgical step to be 20 performed, leaving bony debris at the site of implantation. Generally, small defects at the site of implantation, which are the result of the rather rigorous procedure of tapping screw thread, may be invaded by fibrous tissue, which might be guided through the screw canal.

The present invention aims to provide a new type of fixative device, 25 which may be fixed to bone tissue without the need for prethreading the cavity by tapping screw-thread in the bone tissue. It shall be clear that the word cavity in this context is meant to comprise orifices and other types of holes.

It is further an object of the invention to provide a fixative device having sufficient mechanical strength, and which device may provide a 30 connection to bone tissue having sufficient mechanical strength, so that the

device may be used in various surgical procedures. Another object of the invention is to provide a fixative device for bone tissue, which is made of a biocompatible and biodegradable material.

It has been found that the above goals are reached by using a 5 specific class of copolymers for the manufacture of a fixative device. Surprisingly, the class of copolymers shows a favorable swelling behavior, which behavior may be used to fix a device, based on a member of said class of copolymers, to bone tissue without the use of screw-thread. This specific class 10 of copolymers is formed by copolymers of a polyalkylene glycol terephthalate and an aromatic ester.

Accordingly, the invention relates to a fixative device for bone tissue, which device comprises a copolymer of a polyalkylene glycol terephthalate and an aromatic polyester.

The specific class of copolymers, on which the present device is 15 based, shows a highly favorable swelling behavior in an aqueous environment. The swelling may be as high as approximately 5-100% by volume. The swelling of the copolymer leads to a swelling of the device, which results in a very strong fixation of the device to e.g. bone tissue.

To connect the fixative device to the bone tissue, the device is simply 20 inserted into a cavity provided in the bone, and the swelling causes such expansion of the device that it becomes jammed in the cavity. It has been found that the mechanical strength of the fixation thus provided is sufficient for various purposes in surgical treatment. Accordingly, the tapping of screw-thread in a cavity in bone tissue in which the device is to be fixed is not 25 necessary.

Further, the copolymer is biodegradable. In fact, the biodegradability (the rate of degradation under certain conditions) may be controlled, depending on the envisaged application of the device.

The copolymer on which the present device is based, is a copolymer 30 of a polyalkylene glycol terephthalate and an aromatic polyester. Preferably, the

copolymer comprises 20-90 wt.%, more preferably 40-70 wt.% of the polyalkylene glycol terephthalate, and 80-10 wt.%, more preferably 60-30 wt.% of the aromatic polyester. A preferred type of copolymers according to the invention is formed by the group of block copolymers.

5 The polyalkylene glycol terephthalate may have a weight average molecular weight of about 150 to about 4000. Preferably, the polyalkylene glycol terephthalate has a weight average molecular weight of 200 to 1500. The aromatic polyester preferably has a weight average molecular weight of from 200 to 5000, more preferably from 250 to 4000. The weight average molecular
10 weight of the copolymer preferably lies between 10,000 and 300,000, more preferably between 40,000 and 120,000.

15 The weight average molecular weight may suitably be determined by gel permeation chromatography (GPC). This technique, which is known per se, may for instance be performed using chloroform as a solvent and polystyrene as external standard. Alternatively, a measure for the weight average molecular weight may be obtained by using viscometry (see NEN-EN-ISO 1628-1). This technique may for instance be performed at 25°C using chloroform as a solvent. Preferably, the intrinsic viscosity of the copolymer lies between 0.2289 and 1.3282 dL/g, which corresponds to a weight average
20 molecular weight between 10,000 and 200,000. Likewise, the more preferred ranges for the weight average molecular weight measured by GPC mentioned above can also be expressed in terms of the intrinsic viscosity.

25 In a preferred embodiment, the polyalkylene glycol terephthalate component has units of the formula -OLO-CO-Q-CO-, wherein O represents oxygen, C represents carbon, L is a divalent organic radical remaining after removal of terminal hydroxyl groups from a poly(oxyalkylene)glycol, and Q is a divalent organic radical.

30 Preferred polyalkylene glycol terephthalates are chosen from the group of polyethylene glycol terephthalate, polypropylene glycol terephthalate, and polybutylene glycol terephthalate and copolymers thereof, such as poloxamers.

A highly preferred polyalkylene glycol terephthalate is polyethylene glycol terephthalate.

The terms alkylene and polyalkylene generally refer to any isomeric structure, i.e. propylene comprises both 1,2-propylene and 1,3-propylene, butylene comprises 1,2-butylene, 1,3-butylene, 2,3-butylene, 1,2-isobutylene, 1,3-isobutylene and 1,4-isobutylene (tetramethylene) and similarly for higher alkylene homologues. The polyalkylene glycol terephthalate component is preferably terminated with a dicarboxylic acid residue -CO-Q-CO-, if necessary to provide a coupling to the polyester component. Group Q may be an aromatic group having the same definition as R, or may be an aliphatic group such as 10 ethylene, propylene, butylene and the like.

The polyester component preferably has units -O-E-O-CO-R-CO-, wherein O represents oxygen, C represents carbon, E is a substituted or unsubstituted alkylene or oxydialkylene radical having from 2 to 8 carbon 15 atoms, and R is a substituted or unsubstituted divalent aromatic radical.

In a preferred embodiment, the polyester is chosen from the group of polyethylene terephthalate, polypropylene terephthalate, and polybutylene terephthalate. A highly preferred polyester is polybutylene terephthalate.

The preparation of the copolymer will now be explained by way of 20 example for a polyethylene glycol terephthalate/polybutylene terephthalate copolymer. Based on this description, the skilled person will be able to prepare any desired copolymer within the above described class. An alternative manner for preparing polyalkylene glycol terephthalate/polyester copolymers is disclosed in US-A-3,908,201.

A polyethylene glycol terephthalate/polybutylene terephthalate 25 copolymer may be synthesized from a mixture of dimethyl terephthalate, butanediol (in excess), polyethylene glycol, an antioxidant and a catalyst. The mixture is placed in a reaction vessel and heated to about 180°C, and methanol is distilled as transesterification proceeds. During the 30 transesterification, the ester bond with methyl is replaced with an ester bond

with butylene and/or the polyethylene glycol. After transesterification, the temperature is raised slowly to about 245°C, and a vacuum (finally less than 0.1 mbar) is achieved. The excess butanediol is distilled off and a prepolymer of butanediol terephthalate condenses with the polyethylene glycol to form a 5 polyethylene/polybutylene terephthalate copolymer. A terephthalate moiety connects the polyethylene glycol units to the polybutylene terephthalate units of the copolymer and thus such a copolymer also is sometimes referred to as a polyethylene glycol terephthalate/polybutylene terephthalate copolymer (PEGT/PBT copolymer).

10 Depending on the specific circumstances under which a fixative device according to the invention is intended to be used, the copolymeric material described above may be used in either a porous or a dense, non-porous form. A porous structure enables ingrowth of tissue, for instance of bone tissue. In general, when the fixative device is a suture anchor this type of 15 tissue ingrowth is desired. The skilled person will be able to judge under which circumstances a porous or a dense structure will be preferred.

20 Optionally, the above copolymer may be combined with other materials in the manufacture of a fixative device according to the invention. It may for instance be advantageous to provide a material that facilitates bone ingrowth at the distal end of the device that fits into the bone. Examples of 25 such a material include metals, such as tantalum or Ti6Al4V, or ceramics, such as calcium phosphates. Preferably, the material is a porous metal. In a preferred embodiment, this material may comprise a coating, e.g. as described in the European patent application 98203085.0. Thus, in accordance with this embodiment, the device is composed of different parts which are attached to each other.

30 The device in accordance with this embodiment may be assembled by injection molding the copolymeric material onto the material that facilitates bone ingrowth. Particularly when the latter is a porous material, the melt of the copolymer may penetrate the porous structure of said material. Generally,

it will be preferred that the copolymer penetrates into the porous structure to a depth of 1-5 mm, more preferably 3-4 mm, depending on the size of the device to be manufactured and its specific application.

A fixative device for bone tissue according to the present invention may be used in any application wherein conventional fixative devices for bone tissue are applied. As has been mentioned above, one of the great advantages of the invention is that it is not necessary to provide a cavity in bone tissue with screw-thread in order to fix the present device to the bone tissue. The swelling behavior of the device provides sufficient mechanical strength for the device to be used without the use of screw-thread. Furthermore, the specific copolymer on which the present fixative device is based, is capable of actively providing a bond with bone tissue.

In order to fix a device according to the invention to bone tissue, the device should be in a non-swollen condition. Preferably, the device is in a substantially moist-free condition when applied to bone. It is preferred that the device has a moisture content of less than 1%, more preferably less than 0.1%. These low moisture contents further have been found to have a favorable effect on the shelf life of the device.

Once the device has been placed into a cavity in bone tissue, the device is wetted in order to make it swell. Due to the presence of body and wound fluids surrounding the site of implantation of the device, the device takes up moisture and may swell to an extent of up to 5-100% of its original volume. The increase in volume fixes the device in its place. In particular, expansion of the device in the cavity causes increased pressure on the walls thereof. This in turn increases friction between the walls of cavity and the device, which provides increased mechanical resistance, and thus increased mechanical strength.

Advantageously, it has been found that the fixation of the device thus obtained is able to withstand a force up to or higher than the breaking strength of common suture threads, e.g. a force up to or higher than 200 N.

Using a copolymer described hereinabove, any fixative device for bone tissue may be manufactured. Examples of fixative devices include bone screws, suture anchors, staples, both tapered and non-tapered pins, and so forth. In principle, any type of fixative device may be manufactured which 5 device may be fixed to human tissue due to its swelling behavior.

The invention will now be elucidated on the basis of two preferred embodiments, shown in a drawing. In the drawing:

fig. 1 shows a first embodiment of a fixative device according to the invention fixating an anterior cruciate ligament to a tibia and a femur;

10 figs. 2A and 2B show a plan and side view of a second embodiment of a fixative device according to the invention respectively;

fig. 3 shows the fixative device according to figs. 2 connecting a ligament to a bone;

15 Fig. 4 shows a partial cross section of a third embodiment of a fixative device according to the invention fixating an anterior cruciate ligament to a tibia and a femur;

Fig. 4A shows a plan view of the ligament ends tied in a knot around the fixative device of Fig. 4;

Fig. 4B shows a cross section of the fixative device of Fig. 4;

20 Fig. 4C shows a plan view of the ligament ends before being tied in a knot around the fixative device of Fig. 4;

25 Fig. 5A shows a perspective view of a reinforcing rod and Figs. 5B to 5D a cross sectional view of a bone having a cavity in which the reinforcing rod and the fixative device is inserted;

Fig. 6A shows a perspective view of a fourth embodiment of a fixative device; and

Fig. 6B shows a cross sectional view of a bone in which the fixative device of Fig. 6A has been inserted.

The figures are schematic representations of preferred embodiments of the invention and serve as illustrations only. In the figures, identical or corresponding parts are designated by the same reference numerals.

Figure 1 shows a first embodiment of the invention wherein the 5 fixative devices 1 are used for fixation of an anterior cruciate ligament 2 to the tibia 3 and femur 4. Holes have been drilled in both the tibia 3 and the femur 4. In at least one of these holes, the fixative devices 1 which are constructed as expansion bodies are fitted in dry, unswollen state together with the anterior cruciate ligament 2. The fixative devices 1 will swell up due to the presence of 10 body fluids. If desired, the swelling may be facilitated or accelerated by provision of additional moisture. The swelling will jam the anterior cruciate ligament 2 in the holes provided in the tibia 3 and the femur 4, thus holding the anterior cruciate ligament 2 in place.

Figures 2 and 3 show a second embodiment of the fixative device 1. 15 as a suture anchor 5. The suture anchor comprises an expansion body 1 of substantially cylindrical shape. The expansion body 1 comprises two bores or channels 6 through which a suture thread 7 is provided. This suture thread 7 is preferably made of biodegradable material, for instance also of a copolymer of a polyalkylene glycol terephthalate and an aromatic ester. As has been 20 mentioned above, the expansion body 1 could be composed of two different materials, the lower part being made of the copolymer of a polyalkylene glycol terephthalate and an aromatic ester, and the upper part of a material that facilitates bone ingrowth, such as (porous) tantalum.

In order to attach a ligament 8 to a bone 9, first a hole is drilled in 25 the bone 9 through the cortical bone 10 into the spongy bone 11. In this hole, the suture anchor 5 is placed. The suture thread 7 of the suture anchor is used to fix the ligament 8 to the bone, for instance by means of a knot. Due to the presence of moisture, the cylindrical expansion body 1 of the suture anchor will swell and fix the device into place. As the copolymer expands easily in the

compressible spongy bone surroundings than in the firm cortical bone surroundings, the suture anchor will become wedged firmly in place.

Fig. 4 shows a third embodiment wherein the fixative device 1 is used as an ACL plug for fixation of an anterior cruciate ligament (ACL) 2. The 5 ligament 2 is connected to the femur 4 in a conventional manner, e.g. the cruciate ligament 2 extends through a hole 13 drilled in the femur 4 and comprises two tendons which are looped over a pin 14 extending transversely through the hole 13, such that the ligament 2 is anchored to the femur 4.

The ligament 2 which comprises the four end portions 2A-2D of the 10 looped tendons extends through a hole 15 which is drilled in the tibia 3. To secure the ligament ends 2A-D in the tibial hole 15, a fixative device 1 is introduced. The fixative device 1 comprises an elongated, substantially cylindrical body extending along a central axis A, having a portion of its outer surface 16 forming the cylinder mantle provided with screw thread 17. The 15 fixative device 1 is made of a copolymer of a polymer alkylene and aromatic polyester. The screw thread 17 has a pitch extending in the direction of axis A, such that, even if the fixative device is made of relatively flexible material, insertion into the tibial hole 15 can be performed relatively easily. The fixative device 1 is provided with a head portion 17A with a drive surface for 20 engagement with a tool for rotationally driving the fixative device about the axis A of the tibial hole 15. The drive surface may e.g. comprise a screw type serration 18 for engagement by a screw driver or a square or hexagonal head for engagement by e.g. a wrench. By providing the screw thread 17 with blunt edges or with a square cross section, the chance of damaging the ligament ends 25 2A-2D can be reduced.

The free ends 2A-2D of the ligament 2 may be secured to the fixative device by a knot K. In particular, the knot K can be formed by looping each free end around the mantle of fixative device 1 such that it is interposed between the mantle of the fixative device and an adjacent ligament end in 30 clockwise or counter clockwise direction as is shown in Fig. 4A. After securing

them to the fixative device, the loose ends of the ligaments 2A-2D may be cut off as shown. Preferably, the tibial hole 15 is provided with an enlarged entrance portion E for accommodating the knot K and/or a head portion 17A having an enlarged diameter relative to the elongate body. This way it can be 5 achieved that the knot K does not extend outwardly relative to the bone 3 and the skin surface can remain smooth. In an advantageous manner, any portion of the fixative device 1 protruding beyond the bone surface S, e.g. the head portion 17, may be cut off to the surface level of the bone as indicated in Fig. 4B. By tying the free ligament ends 2A-2D in a knot K around the mantle 10 surface 16 of the fixative device 1 the need for additional clamps is obviated.

A presently most preferred way of tying the free ends 2A-2D in a knot K around the fixative device 1 is in a reef knot as discussed in relation to Fig. 4C. First, free end 2A is moved clockwise to extend over free end 2B (to the bottom left of Fig. 4C). Next, free end 2B is moved clockwise to extend over 15 free end 2A and 2C (to the top left of Fig. 4C). Subsequently, free end 2C is moved clockwise over free ends 2B and 2D (to the top right of Fig. 4C). Finally, free end 2D is moved clockwise to extend over free end 2A (to the bottom right of Fig. 4C) and is tucked in between the mantle 16 of the fixative device and the free end 2A and is pulled tight.

20 It shall be clear that the above described method for tying the free ends of the ligaments to the fixative device extending from the tibial hole may also be used in combination with fixative devices that are made of non-swelling, biocompatible material e.g. titanium.

As the fixative device 1 is introduced in dry, unswollen state it will 25 initially fix the ligament ends 2A-2D to the walls of the tibial hole 15 by means of increased friction due to contact pressure. After introduction, the fixative device 1 will pick up fluid from its natural surroundings and/or from additional moistening.

The resulting swelling will further press the ligament ends 2A-2D 30 against the bony wall of the tibia hole 15. At a later stage, the bone material

and the material of the fixative device may grow into contact with each other and the material of the fixative device may be replaced by bone material due to bone ingrowth.

To enhance ingrowth of bone material, the fixative device 1 may be
5 formed as a composite including calcium phosphate. In particular, the calcium phosphate may be applied as a coating as discussed in European patent application 99202281.4 and/or as a mixture as disclosed in European patent application 99203141.9, the text of which applications is herein incorporated by reference.

10 It shall be clear that this embodiment may also be used to fix other types of ligaments or sutures to the walls of an aperture.

Figures 5A-5D show that the fixative device 1 may be used in combination with a supporting rod 19 made of stiff and tear resistant material. The supporting rod 19 may be provided with loops 20 to guide the suture 7
15 along the supporting rod 19. Fig. 5B shows that the supporting rod 19 with the attached suture thread 7 may be introduced in a tilted position through a hole 21 in the bone 9 into an underlying larger cavity 22 in the bone 9. The hole 21 and the underlying undercut cavity 22 can be made by a surgeon using a suitable instrument, e.g. a cylindrical or spherical burr. After insertion, the
20 supporting rod 19 is tilted in the direction of arrow 23, such that it extends transversely in the hole 22 as shown in Fig. 5C. When a pulling force is applied to the ends of the suture thread 7, the supporting rod 19 is locked into place as its length is chosen larger than the diameter of the hole 21. The hole 21 is subsequently closed by a fixative device 1, such that the hole is locked.

25 Figs. 6A and 6B show yet another embodiment of the fixative device 1. The fixative device 1 comprises a substantially cylindrical body of swellable material, which has been provided with longitudinal grooves 24 in its mantle surface to guide the suture thread 7. The fixative device 1 is further provided with a reinforcing portion 19A for distributing the pressure applied by the
30 suture thread 7. The reinforcing portion 19A comprises a material having a

relatively high stiffness and tear resistance, which may exhibit a lower degree of swelling. The reinforcing portion is preferably cylindrical, such that the pressure exerted by the suture thread 7 can be distributed evenly. As shown in cross section in Fig. 6B, the suture thread 7 can still be moved through the 5 slots 24 and over the reinforcing portion in a sliding manner. The fixative device 1 itself is locked in the hole in a manner as described in relation to Fig. 3.

It will be clear that the invention is not limited to the described preferred embodiments and merely show the principles underlying the 10 invention. For example, the expansion body may have various shapes and/or surface textures, e.g. cylindrical, frusto conical or block-shaped. In addition, the shape of the expansion body may vary at different locations, e.g. a cylindrical body may be provided with a convex tip. Furthermore, the cavity of the bone into which the fixative device is to be inserted, may be provided with undercuts to increase the immediate anchoring capacity of the fixative device. 15

In addition, the fixative device may be provided with protrusions or areas of increased swelling capacity to increase the anchoring or jamming function. Furthermore, the expansion body may be connected to various other types of sutures, e.g. staples or clamps. In addition, the fixative device may 20 comprise a number of swelling bodies and the fixative device may be provided with connecting means, e.g. a socket or similar means for accommodating objects or e.g. an arm carrying a connector.

Such embodiments are within the scope of the invention as defined in the appended claims.

25 The invention will now be further elucidated by the following, non-restrictive example.

EXAMPLE

A cylinder (diameter 1.5 cm, height 3 cm) of a copolymer of 30 polyethylene glycol terephthalate (Mw = 574) and polybutylene terephthalate

(Mw = 800), comprising 60 wt.%, based on the weight of the copolymer, of the polyethylene glycol terephthalate, was provided with two holes in axial direction (diameter 0.5 mm). Through these holes, a Vicryl™ mulitfilament thread (length 0.5 m) was provided to obtain a device as shown in Figure 3.

5 In a bovine femur, a hole was drilled through the cortical bone into the spongy bone of a diameter of 1.55 cm. The device was fitted into this hole in a dry state (moisture content below 0.5%). Next, the device was wetted using 100 ml water. As a result, the device swelled and was fixed to the bone. After 12 hours, a force of around 100 N was applied to the thread without the
10 device showing any movement in the hole.

Claims

1. A fixative device for bone tissue, which device comprises a copolymer of a polyalkylene glycol terephthalate and an aromatic polyester.
2. A device according to claim 1, wherein the aromatic polyester is formed from an alkylene glycol terephthalate having from 2 to 8 carbon atoms and an aromatic dicarboxylic acid.
3. A device according to claim 1 or 2, wherein the polyalkylene glycol terephthalate is chosen from the group of polyethylene glycol terephthalate, polypropylene glycol terephthalate, polybutylene glycol terephthalate, and copolymers thereof.
4. A device according to any of the preceding claims, wherein the polyester is chosen from the group of poly(ethyleneterephthalate), poly(propyleneterephthalate), and poly(butyleneterephthalate).
5. A device according to any of the preceding claims, wherein the copolymer is a polyethylene glycol terephthalate/poly(butyleneterephthalate) copolymer.
6. A device according to any of the preceding claims, wherein the copolymer comprises 20-90 wt.%, preferably 40-70 wt.%, of the polyalkylene glycol terephthalate.
7. A device according to any of the preceding claims, wherein the polyalkylene glycol terephthalate has a weight average molecular weight of from 150 to 4000, preferably from 200 to 1500.
8. A device according to any of the preceding claims, further comprising a material that facilitates bone ingrowth.
9. A fixative device according to any of the preceding claims, comprising at least one swelling body including said copolymer.
10. A fixative device according to claim 8, further comprising connecting means for connecting objects thereto.

11. A device according to any of the preceding claims, being a bone screw, a suture anchor, an ACL plug, a tapered or non-tapered pin, or a staple.
12. A device according to any of the preceding claims, comprising an elongate body portion extending along a central axis, the elongate body portion being on an outer surface thereof provided with screw thread, the pitch of the screw thread extending in axial direction.
13. A device according to claim 12, wherein the elongate body carries a head portion that is provided with at least one drive surface for engaging a driving tool.
14. A suture anchor according to any of claims 9-13, comprising a biodegradable multifilament or monofilament for connection to muscle or ligament tissue.
15. The use of a swellable copolymer of a polyalkylene glycol terephthalate and an aromatic polyester for fixing a device to bone tissue.
16. A method of fixating a ligament to a bone, comprising:
 - drilling a hole through the bone and axially feeding the ligament through the hole, such that free ends of the ligament extend from an end of the hole,
 - axially inserting an elongate fixative device into the hole to press the ligament device into engagement with the wall of the hole; and
 - tying the free ligament ends in a knot around a mantle surface of the fixative device.

1/8

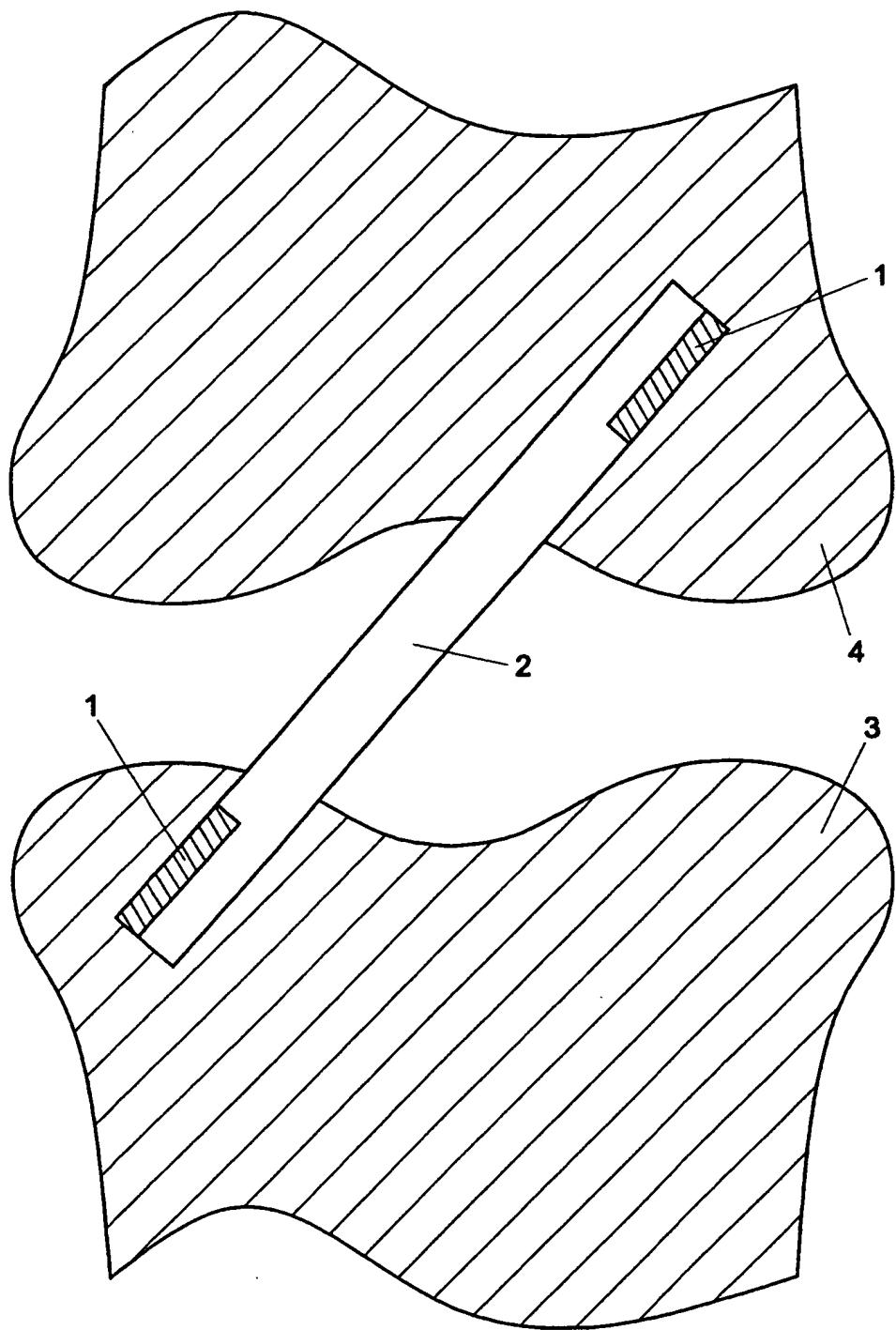


Fig. 1

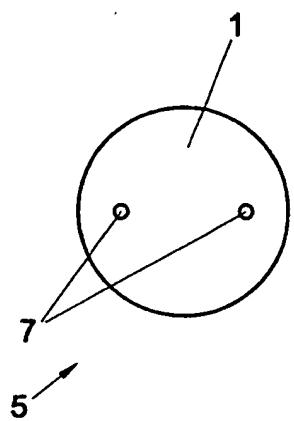


Fig. 2a

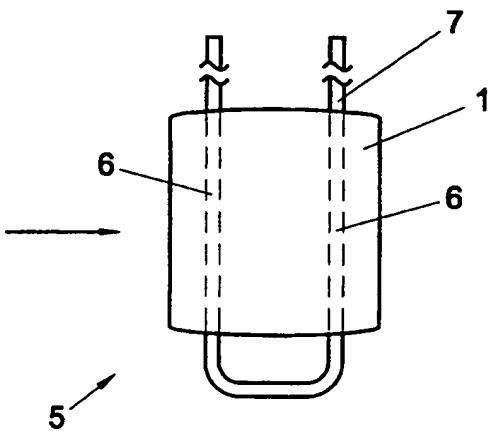


Fig. 2b

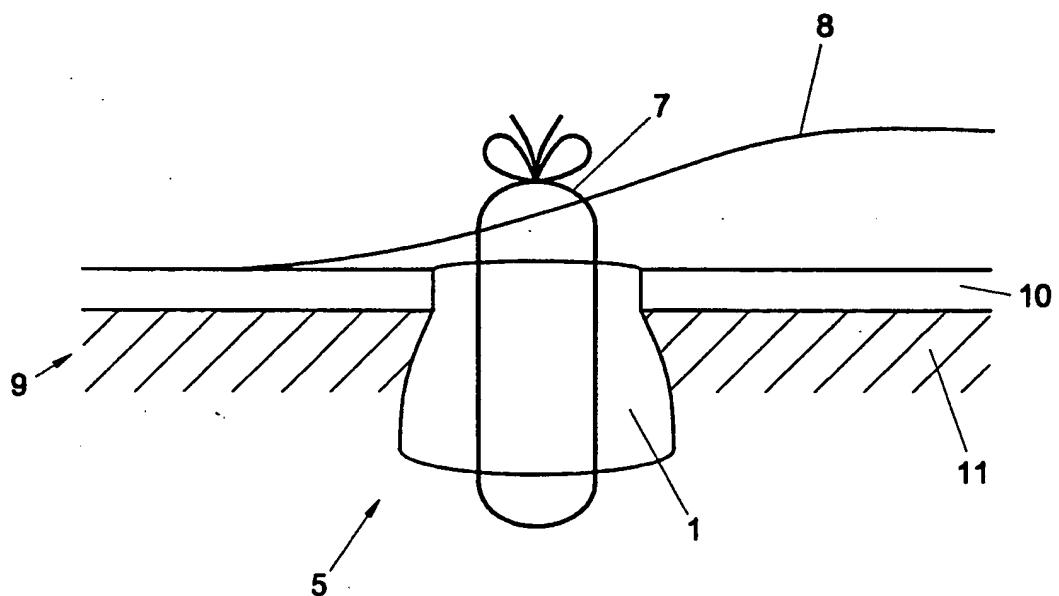


Fig. 3

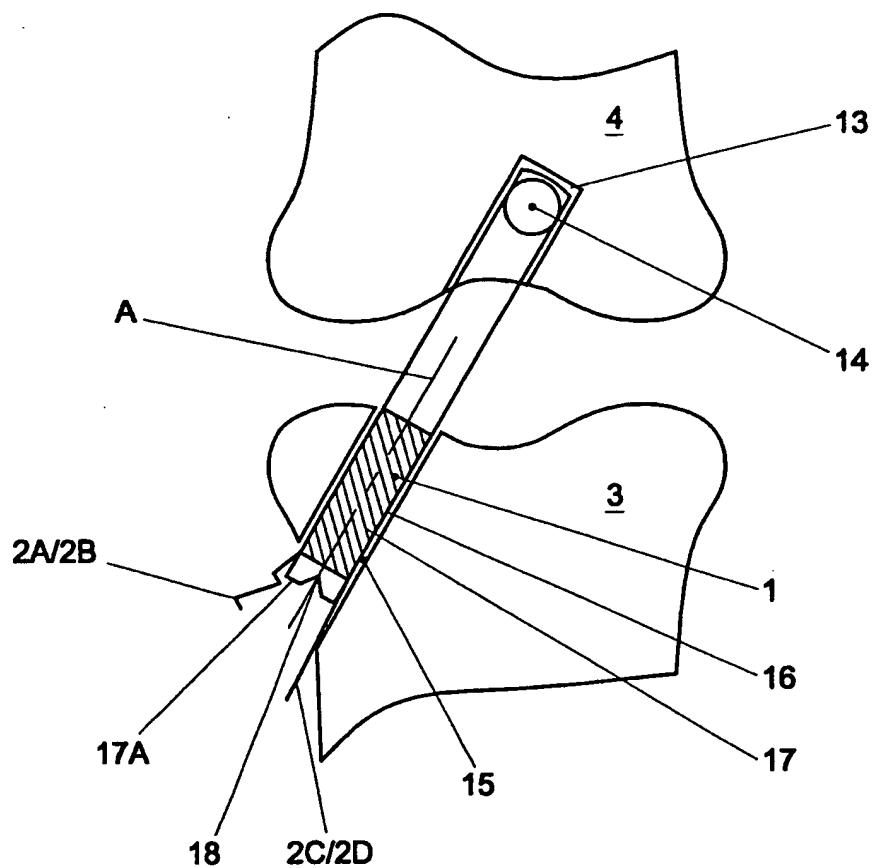


Fig. 4

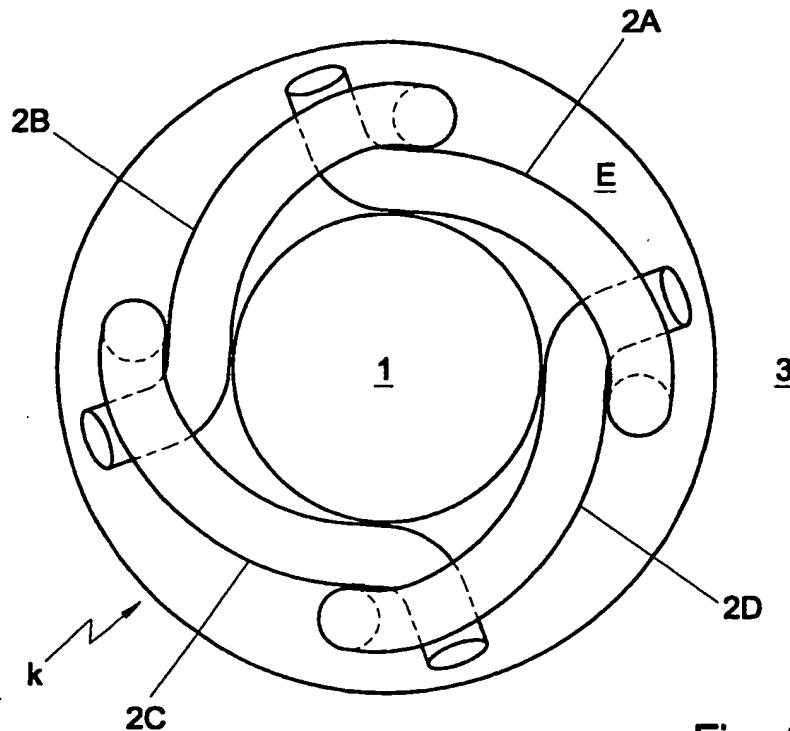


Fig. 4A

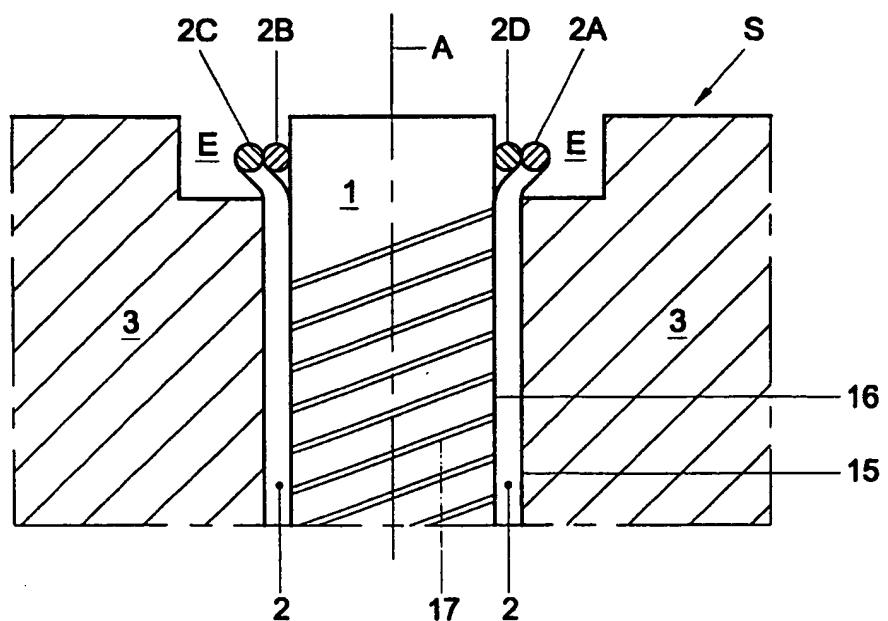


Fig. 4B

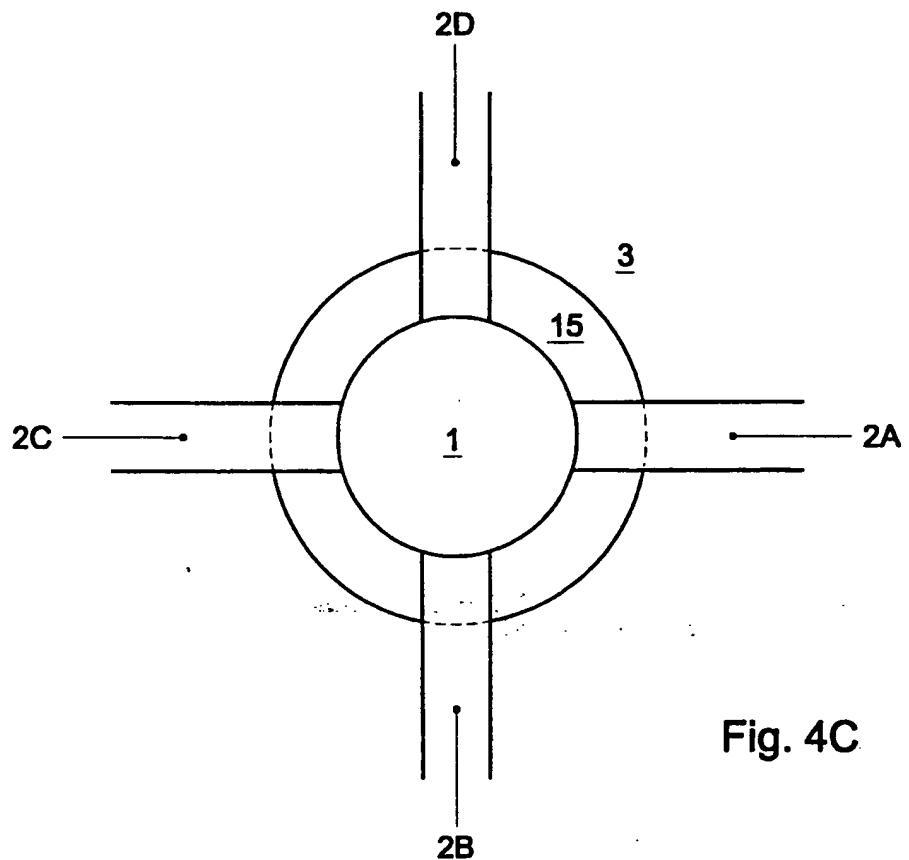


Fig. 4C

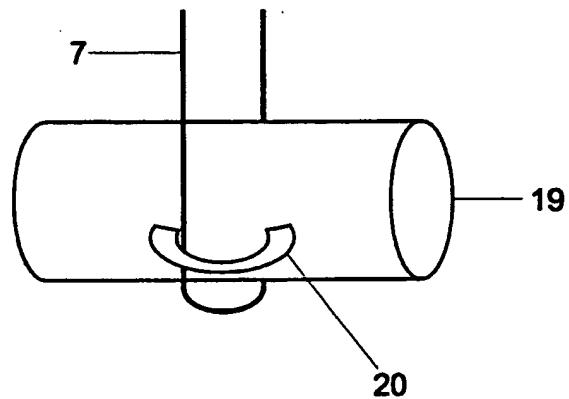


Fig. 5A

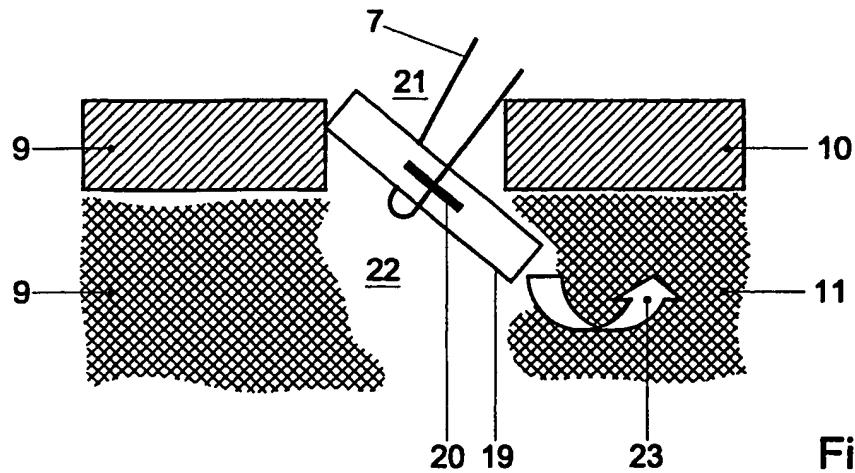


Fig. 5B

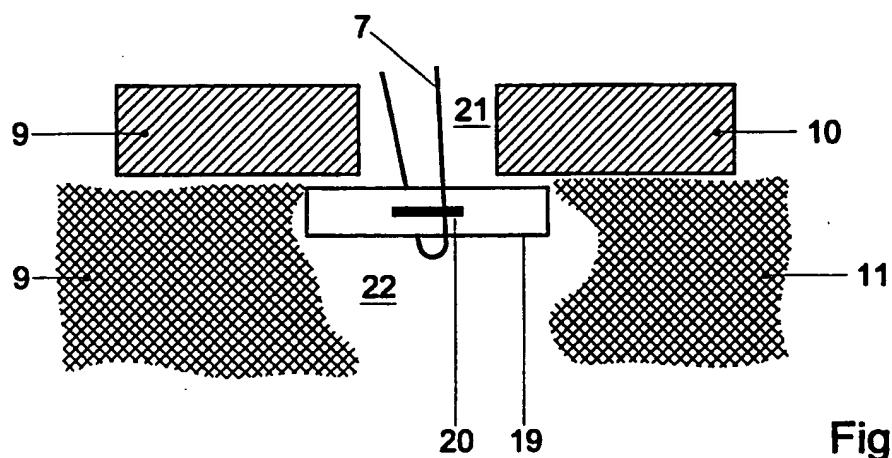


Fig. 5C

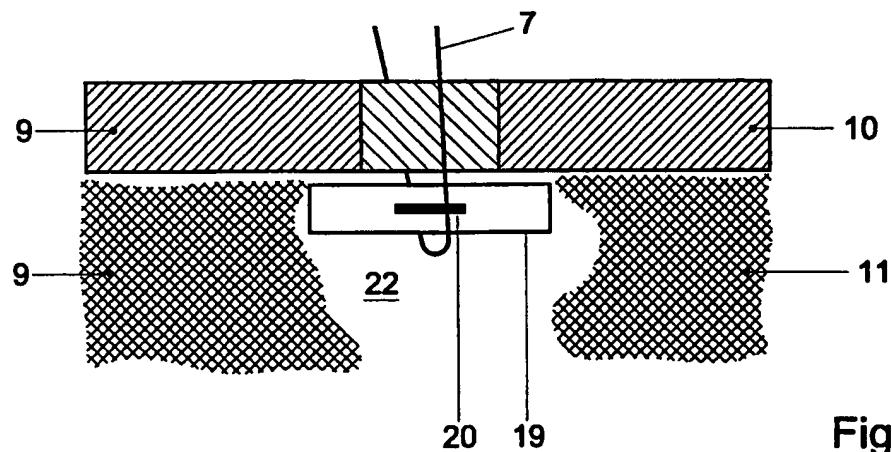


Fig. 5D

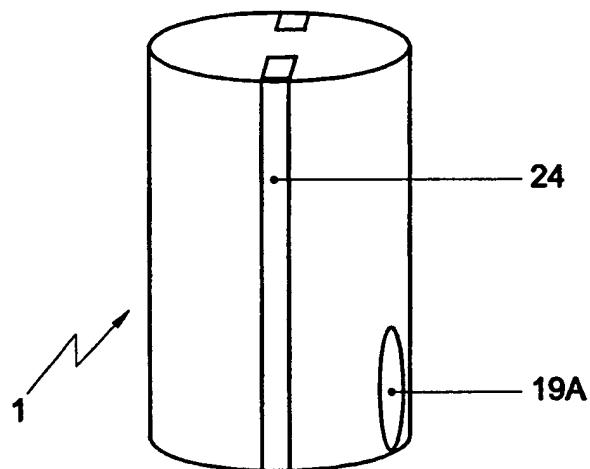


Fig. 6A

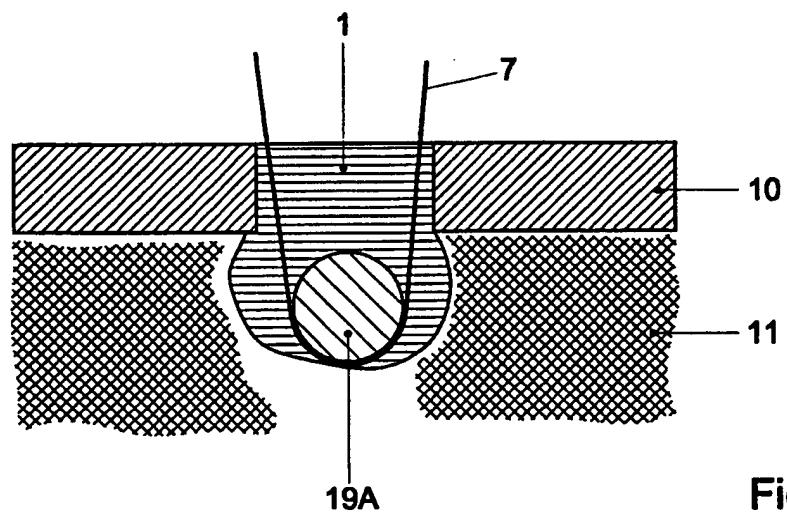


Fig. 6B

INTERNATIONAL SEARCH REPORT

International Application No

PCT/NL 00/00555

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61L31/06

Applicant(s) referred to International Patent Classification (IPC) or to both national classification and IPC

B. SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 357 155 A (STICHTING VOOR DE TECHNISCHE WETENSCHAPPEN) 7 March 1990 (1990-03-07) page 3, line 50; claims 1-6	1-7, 11, 14
X	WO 95 29201 A (COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION) 2 November 1995 (1995-11-02) page 6, line 20 - line 23; claims 1,3,8,9,26,27; example 1	1,2,4,6, 7,11,14
X	US 5 312 435 A (NASH J.) 17 May 1994 (1994-05-17) column 5, line 12 - line 16; claims 1,3,4	1-5, 9, 11,14,15
A	EP 0 891 783 A (ISOTIS) 20 January 1999 (1999-01-20) page 5, line 27 - line 31	1-7

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the International filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the International filing date but later than the priority date claimed

"T" later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"Z" document member of the same patent family

Date of the actual completion of the International search

2 October 2000

Date of mailing of the International search report

17/10/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5816 Patentstaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax. (+31-70) 340-3016

Authorized officer

Peltre, C

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/NL 00/00555

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP 357155	A 07-03-1990	NL 8802178 A		02-04-1990
		AT 105490 T		15-05-1994
		DE 68915229 D		16-06-1994
		DE 68915229 T		17-11-1994
		ES 2056195 T		01-10-1994
		KR 140538 B		15-06-1998
WO 9529201	A 02-11-1995	AU 681515 B		28-08-1997
		AU 2249695 A		16-11-1995
US 5312435	A 17-05-1994	NONE		
EP 891783	A 20-01-1999	CA 2243248 A		16-01-1999